

K111231

Section 6- 510(k) Summary

JUL 13 2011

a. Owner/Company name, address

THE YOSHIDA DENTAL MFG. CO., LTD.
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Michizo Yamanaka
President

▪ **Contact person**

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b. Contact/Application Correspondent

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c. Date prepared

April 29, 2011

d. Name of device

Trade Name: PANOURA 18S
Common Name: Extraoral source x-ray system
Classification Name: System, x-ray, extraoral source, digital
Classification Regulation: 21 CFR 872.1800

e. Predicate devices

The PANOURA 18S is substantially equivalent to the following legally marketed device:

510(k):	K093683
Trade name:	ORTHOPANTOMOGRAPH OP300
Product code:	MUH

The predicate device is hereinafter called "the ORTHOPANTOMOGRAPH (k093683)" in this application.

f. Description of the device

The PANOURA 18S dental panoramic and cephalometric device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray images as well as X-ray projection images. The PANOURA 18S is equipped with an X-ray generator and a Sensor unit at Arm unit supported by Column unit and Sliding body unit. While rotating around the patient's teeth and jaw, the PANOURA 18S irradiates X-ray and detects X-ray absorbed data at the Sensor unit multiple times. Detected multiple data are transferred to an image processing unit and the data are superimposed with appropriate shift value according to the X-ray moving speed from the arm rotation to acquire image.

g. Indications for Use

The PANOURA 18S dental panoramic and cephalometric device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray images as well as X-ray projection images. The device must only be operated and used by dentists and other legally qualified professionals.

h. Statement of substantial equivalence

The characteristics of the PANOURA 18S are similar to those of the ORTHOPANTOMOGRAPH (k093683) listed in part e. The similarities are:

- Intended use
- Operational characteristics
- Ionizing radiation
- Cephalometric radiogram
- Panoramic images by producing conventional 2D X-ray images as well as X-ray projection images

Difference regarding intended use between the PANOURA 18S and the ORTHOPANTOMOGRAPH (k093683) is that the ORTHOPANTOMOGRAPH (k093683) has following additional intended use compared to the PANOURA 18S:

1. Cone Beam Computerized Tomography
2. Producing X-ray projection of 3-D

In order to evaluate safety and effectiveness of the PANOURA 18S, software verification/validation, performance testing, and risk analysis were performed. In conclusion,

those testing and analysis demonstrated that the PANOURA 18S did not raise any new safety or effectiveness concerns compared to the ORTHOPANTOMOGRAPH (k093683)

i. Comparison table

Table 6-1 compares the characteristics between the PANOURA 18S and the ORTHOPANTOMOGRAPH (k093683).

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Table 6-1. Comparison Table

PANOURA 18S			ORTHOPANTOMOGRAPH (K093683)		
Device Characteristics			Digital panoramic x-ray equipment		
Equipment type			Digital panoramic x-ray equipment		
Mode of operation			Continuous operation with intermittent load		
X-ray tube focal point			0.5 mm×0.5 mm		
X-ray tube cooling method			Oil cooling		
Nominal maximum electric power (combination of X-ray tube voltage and tube current at maximum output)			0.82kW (82kV, 10mA) 1.44kW (90kV, 16mA)		
Tube voltage			58 - 82kV		
Tube current			2.0 - 10mA		
Radiation time	Panoramic	Adult	8, 14, 16s		
		Child	6.4, 11.2, 12.8s		
	TMJ		8s		
	Cephalo / Carpus image acquisition		8 - 10 s		
	Electric power supply resistance			Maximum 0.2 Ω	
Total filtration			2.5mmAl equivalent or over		
Leakage dose			1.0 mGy/h or less		
Leakage dose calculation standards			Tube voltage 82kV, tube current 10mA		
Rated power	Number of phases		Single phase		
	Frequency		50 / 60 Hz		
	Voltage		AC100V - 120V / AC220V - 240V		
	Input		110VAC 230VAC		
Classification			Class I, Type B		
			Class I, Type B		

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Device Characteristics		PANOURA 18S	ORTHOPAN N10 MOGRAPH (K093683)
Weight		125kg Standing position wall mount	200kg (Panoramic)
		120kg Standing position wall mount (short type)	
		150 kg (with an optional base)	
		145kg Standing position base mount short type with an optional base/ 150kg with wide base	
		190kg Standing position wall mount (with Cephalo)	240kg (Cephalo)
		185kg Standing position wall mount short type (with Cephalo)	
		215kg Standing position base mount with Cephalo and optional base	
		210kg Standing position base mount short type with Cephalo and optional base/ 215kg with wide base	
		2209 x 849 x 1192mm(Standing position wall mount)	2410 x 830 x 1126mm (standard column)
		2209 x 1759 x 1192mm(Standing position wall-mount with Cephalo)	2410 x 1931 x 1193 mm (with Cephalo*)
Size			
EMC Classification		Class A	Class B
		15 degrees	5 degrees
		Horizontal scan, synchronized sensor and secondary slot motion	Horizontal scan, synchronized sensor and secondary slot motion
		8 - 10s	10 - 20s
Cephalometric radiogram	Scanning method		
	Scanning time		

j. Compliance with recognized consensus or voluntary standards

The following recognized consensus or voluntary standards were used (as applicable) for the Extraoral source x-ray system classified in 21 CFR 872.1800. The PANOURA 18S meets the requirements of the recognized consensus or voluntary standard.

Standards No.	Standards Organization	Standards Title	Date
60601-1	UL	Medical Electrical Equipment, Part 1: General Requirements for Safety , A1:1991/A2:1995	2003
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. A1:2004	2004
60601-1-3	IEC	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	1994
60601-2-7	IEC	Medical electrical equipment - Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	1998
60601-2-28	IEC	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	1993
60601-2-32	IEC	Medical electrical equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment	1994
60825-1	IEC	Safety of laser products - Part 1: Equipment classification and requirements	2007
61223-3-4	IEC	Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment	2000
62304	IEC	Medical device software - Software life cycle processes	2006
14971	ISO	Medical devices - Application of risk management to medical devices	2007

k. Conclusion

The PANOURA 18S has the same intended use except regarding computerized tomography and reconstructed 3-D image and similar operational and technological characteristics as the ORTHOPANTOMOGRAPH (k093683). The performance test results indicate that the PANOURA 18S meets the requirements of recognized consensus or voluntary standard. Based on the information presented above regarding substantial equivalence to the ORTHOPANTOMOGRAPH (k093683), THE YOSHIDA DENTAL MFG. CO., LTD. concludes that the PANOURA 18S is substantially equivalent to the ORTHOPANTOMOGRAPH (k093683) and does not raise any new questions regarding safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Re: K111231

JUL 13 2011

Trade/Device Name: Panoura 18S
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: April 29, 2011
Received: May 2, 2011

Dear Dr. Kanai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

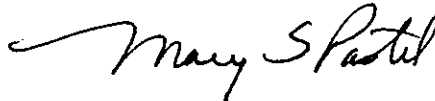
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, reading "Mary S. Pastel". The signature is fluid and cursive, with the first name "Mary" being more prominent than the last name "Pastel".

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): _____

Device Name: PANOURA 18S

Indication for Use

The PANOURA 18S dental panoramic and cephalometric device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray images as well as X-ray projection images. The device must only be operated and used by dentists and other legally qualified professionals.

Prescription Use **X**
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary Spotal
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111231